UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Master File No. 1:01-cv-12257-PBS Sub-Category Case No. 1:08-cv-11200
THIS DOCUMENT RELATES TO: *United States ex rel. Linnette Sun and Greg Hamilton, Relators,* *v.* *Baxter Healthcare Corporation.*	Judge Patti B. Saris

REPLY MEMORANDUM OF BAXTER HEALTHCARE CORPORATION IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT

Relators' opposition memorandum[1] to Baxter's motion for partial summary judgment[2] makes two basic arguments. First, Relators contend that the Settlement Agreement and Release between Baxter and Ven-A-Care,[3] as consented to by the United States, should not be read to mean what it says because the United States did not intend to release any claims that "are not present in the Ven-A-Care complaint." Relators' Memorandum at 1. Second, Relators argue that their Advate claim is not subject to dismissal on the alternative ground of government knowledge and acquiescence because "generalized knowledge of AWP manipulation" is not a

[1] Relators' Memorandum in Opposition to Defendant Baxter Healthcare Corporation's Motion for Partial Summary Judgment, filed November 15, 2011 ("Relators' Memorandum").

[2] Baxter Healthcare Corporation's Motion for Partial Summary Judgment, filed October 19, 2011. Our arguments in support are set forth in Memorandum of Baxter Healthcare Corporation in Support of Its Motion for Partial Summary Judgment ("Baxter's Memorandum").

[3] Exhibit EE to Declaration of Shamir Patel in Support of Baxter Healthcare Corporation's Motion for Partial Summary Judgment, filed October 19, 2011 ("Settlement Agreement and Release").

viable defense. *Id.* at 2. Both arguments ignore the main points made in Baxter's opening paper, and both depend upon fundamentally wrong views of the governing law.

Relators' first argument suggests that the Settlement Agreement and Release "hoodwinks" people who may not know that Labeler Code 00944 includes Advate. This argument completely ignores the release's main text. Nowhere do Relators mention, much less discuss, the crucial, all-encompassing language that precedes the mention of Labeler Code 00944. The Settlement Agreement and Release first explicitly releases pricing claims as to "*any and all drugs* manufactured, marketed and/or sold by or on behalf of any Baxter Party" from June 23, 1989 through October 11, 2011. Settlement Agreement and Release Sections II.E., II.J., III.7. (emphasis added). Labeler Code 00944 is then identified as a specific *example* – expressly stated to be "without limitation" – of the broader "any and all" Baxter drugs language. Highlighting Labeler Code 00944 is therefore a *second* way of making clear that Baxter blood-clotting therapies sold between 1989 and 2011 are covered by the Settlement Agreement and Release. Part I below demonstrates that, as a matter of law, the Court is obligated to enforce this release by its plain terms and without regard to a subsequent general statement by any single signatory.

Relators' second argument – concerning the merits of their Advate claim – likewise ignores a central point of Baxter's opening brief. We went to considerable lengths in that brief to place Advate's reimbursement in its historical context. *See* Baxter's Memorandum at 4-10. The chronology provided is critical, yet Relators mention none of the dates cited nor, even more fundamentally, the federal court case that was exclusively devoted to Advate reimbursement.

Baxter Healthcare Corp. v. Weems, 643 F. Supp. 2d 111 (D.D.C. 2009) ("*Weems*").[4] Relators ignore the critical fact that Advate was not even commercially available until August 2003. By the time Advate was eligible for reimbursement under Medicare and Medicaid, as addressed in Part II below, the Federal Government was well aware of the specifics of Advate's pricing and the spread between AWP and actual transaction prices. We are not making general arguments about generalized knowledge. Baxter's motion is grounded in the indisputable facts surrounding Advate's reimbursement. As the *Weems* court records reflect, this reimbursement occurred *after* Baxter had provided the Federal Government – specifically, the Centers for Medicare and Medicaid Services ("CMS") – with detailed information concerning Advate's AWPs and Advate's actual transaction prices to hospitals, net of all discounts, rebates, and incentives.

Finally, Part III explains why Relators are not entitled to additional discovery on a "surprise" theory – that is, that the "government knowledge" defense has taken them by surprise. This defense, in one form or another, has been at the heart of this litigation from the beginning. The notion that it is a surprise is frivolous.

I. THE SETTLEMENT AGREEMENT AND RELEASE RESOLVES ALL AWP AND SIMILAR PRICING CLAIMS AGAINST BAXTER FOR "ANY AND ALL" BAXTER DRUGS MANUFACTURED, MARKETED, OR SOLD FROM JUNE 23, 1989 THROUGH OCTOBER 11, 2011

The starting point for interpretation of an agreement is obviously the language of the agreement. Relators nonetheless ignore *all* of the language of the Settlement Agreement and Release except one Labeler Code number. Relators do not mention, much less discuss, the fact that the Settlement Agreement and Release explicitly releases AWP and similar pricing claims

[4] Westlaw and Lexis incorrectly identify this case as *Baxter Healthcare Corp. v. Weeks*. The docket for the United States District Court for the District of Columbia at 08-cv-02204-JR identifies the case as *Baxter Healthcare Corp. v. Weems, et al*.

against Baxter for "*any and all drugs* manufactured, marketed and/or sold by or on behalf of any Baxter Party" from June 23, 1989 through October 11, 2011. Settlement Agreement and Release Sections II.E., II.J., III.7. (emphasis added). The Settlement Agreement and Release's specific, later mention of Labeler Code 00944, which includes Advate, is the opposite of "hoodwinking." *See* Relators' Memorandum at 1. The identification of Labeler Code 00944 provides specific, additional notice as to a group of drugs that are encompassed by the general release language – a category that the Settlement Agreement and Release expressly says is included "without limitation" on the sweeping broader language of "any and all drugs manufactured, marketed and/or sold by or on behalf of any Baxter Party." Settlement Agreement and Release Section II.E. [5]

The Settlement Agreement and Release is to be interpreted in accordance with federal common law, *see generally United States v. Seckinger*, 397 U.S. 203, 209-10 (1970); *Kennewick Irrigation Dist. v. United States*, 880 F.2d 1018, 1032 (9th Cir. 1989), which applies "'common-sense canons of contract interpretation,'" *Smart v. Gillette Co. Long-Term Disability Plan*, 70 F.3d 173, 178 (1st Cir. 1995) (citation omitted). This means the Court must enforce the agreement according to the plain meaning of its terms. *Nault v. United States*, 517 F.3d 2, 4 (1st Cir. 2008). Extrinsic evidence must be disregarded if the contract is unambiguous. *Filiatrault v. Comverse Tech., Inc.*, 275 F.3d 131, 137 (1st Cir. 2001).

The Settlement Agreement and Release *is* unambiguous in its release of "any and all" Baxter drugs sold from June 1989 through October 11, 2011, specifically including, "without

[5] There is nothing surprising about the impact of the Ven-A-Care Settlement Agreement and Release on currently pending State AWP litigations. It would be undisputed, for example, that the federal share of any of the remaining State cases pending against Baxter would have been settled by the Settlement Agreement and Release even though that particular State was not called out in the Ven-A-Care complaint.

limitation," all drugs under Labeler Code 00944, which no one denies encompasses Advate. *See* Relators' Memorandum at 2 n.1. Under these circumstances, it is irrelevant what any of the parties might say now (or ever) about Advate's inclusion. *All* Baxter drugs were specifically included and the additional mention of Labeler Code 00944 leaves no doubt that all of Baxter's blood-clotting therapies, including Advate, are covered.

Baxter agrees with Relators that one of the purposes of the consent requirement of the False Claims Act ("FCA") is to ensure that the United States agrees to the terms of a relator's proposed release. *See* Relators' Memorandum at 6. Indeed, we made this precise point in our opening memorandum, which further explains that the United States in fact objected to the bargained-for release language in a previous AWP *qui tam* case (involving Schering-Plough). Baxter's Memorandum at 12-13. We cited that Justice Department objection as one example of the Government's ability to object when it believes the scope of proposed release language is not commensurate with the consideration to be paid. Such an objection places a settlement and the proposed payments thereunder on hold. But the Government did not object here. To the contrary, the Government expressly consented to the release and then collected $25 million from Baxter in consideration for that release. In addition, we pointed to numerous exceptions to the release that were designed solely to preserve non-FCA claims that the United States was not settling. *Id.* at 13.

Moreover, the United States' general post-settlement statement that "its consent reflected the United States' consent to the dismissal with prejudice only of claims pled in relator Ven-A-Care's complaint" is decidedly unhelpful. First, if, as Relators contend, the Government intended to limit the Settlement Agreement and Release to specifically excluded Advate, the Government could have insisted on such an exclusion in the release language as a condition for

its consent and could have clearly so stated in its post-settlement statement. Second, regardless how this Court might have ruled on the drugs that Ven-A-Care could pursue at trial – a different question from what claims are literally in the Amended Complaint – only one of the three causes of action in Ven-A-care's Amended Complaint (the third) is specifically limited to damages resulting from purchases of Specified Drugs. The first two FCA causes of action are not so limited and do not mention Specified Drugs; they seek all damages flowing from Baxter's allegedly wrongful conduct. These expansive allegations might or might not have been limited by this Court's orders, but they existed in Ven-A-Care's Amended Complaint before this Court dismissed that complaint with prejudice "pursuant to" the Settlement Agreement and Release. Nothing in the United States' statement about its consent for dismissal directly contradicts the plain language of the Settlement Agreement and Release.

Relators direct the Court to a recent "false marking" *qui tam* case under 35 U.S.C. § 292, *Promote Innovation, LLC v. Motorola, Inc.*, No. 6:10cv575 LED, 2011 WL 3610049 (E.D. Tex. Aug. 11, 2011). That case and other recent *qui tam* "false marking" decisions, however, support Baxter's argument. In *Promote Innovation*, the United States *objected* to the terms of the release and specifically refrained from depositing the defendant's settlement check. *Id.* at *5. This objection and act, the court held, preserved the Government's position. In "false marking" cases in which the Government consented to a release and accepted payment, however, federal courts have held the opposite.

One example, cited by the court in *Promote Innovation*, is *Simonian v. Irwin Industrial Tool Co.*, No. 10-1260, 2011 WL 147717 (N.D. Ill. Jan. 18, 2011). In *Simonian*, the court held that because the United States had consented to a settlement releasing "any and all claims" under 35 U.S.C. § 292 and received money in connection with that broad release, the

United States had "relinquished any right to damages" from the released party for violations of the statute. *Simonian*, 2011 WL 147717, at *4. The court specifically rejected the argument Relators advance here – that a second relator's *qui tam* should not be barred because the United States may not have intended by its consent in the settled *qui tam* case to release claims in the second *qui tam* case. *Id.* at *4-6. The release's broad language, the court held, trumped any arguments based upon the Government's possible subjective intent. *Id.* at *5-6. The court specifically held that

> it is irrelevant whether the United States knew of Mr. Simonian's suit when it settled those cases. The FLFMC and Clip Ventures releases were not limited to claims that were known. The broad general releases encompassed both known and unknown claims.[6] The claims in Mr. Simonian's complaint unambiguously fall within the broad releases in the Clip Ventures and FLFMC settlement agreements. Thus, even if the United States was not aware of Mr. Simonian's complaint, the releases extinguish any Section 292 claims against NOC for products marked with the ′148 Patent.

Id.

Similarly, in *San Francisco Technology, Inc. v. Graphic Packaging International, Inc.*, No. 1:10-CV-1195-CAP, 2011 WL 2909275 (N.D. Ga. June 16, 2011), the Government had notice of and consented to the terms of a broad settlement and therefore was bound by those terms. In that case,

> GPI sought and obtained approval of the settlement agreement from the Department of Justice. On behalf of the Department of Justice, John Fargo, the Director of the Intellectual Property Staff with the Commercial Litigation Division, stated that the department did "not object to the settlement and the dismissal order," which he had been asked to review.

[6] Similarly, the Ven-A-Care Settlement Agreement and Release covers "all of the claims that were brought, could have been brought, or could be brought in the future." Settlement Agreement and Release Section III.J.

Id. at *4 (citation omitted). There was thus no basis for the court to amend its judgment and narrow the release to which the United States had consented. *Id.* The court further noted that the Government's consent to the settlement agreement effectively expanded the scope of the relator's assignment beyond the four corners of the relator's complaint. *Id.* at *4-5.

The situation here is the same. Pursuant to 31 U.S.C. § 3730(b)(1), Ven-A-Care and Baxter sought and obtained the approval of the Department of Justice to the Settlement Agreement and Release. The Settlement Agreement and Release in fact was conditioned upon the United States' final written consent (Section III.5.), which the parties agreed would occur *before* Baxter paid the Settlement Amount (Sections III.3., III.5.). On behalf of the Department of Justice, Laurie A. Oberembt, Civil Division, signed that consent on October 3, 2011. Exhibit GG to Declaration of Shamir Patel in Support of Baxter Healthcare Corporation's Motion for Partial Summary Judgment, filed October 19, 2011. Six government attorneys appear in the signature section as representing the United States. *Id.* Baxter subsequently transferred $25 million to the U.S. Treasury to fulfill its payment obligation for the bargained-for release.

The decisions above enforcing the terms of a settlement agreement as written under similar circumstances are simply applications of what the First Circuit has called the "'common-sense canons of contract interpretation'" that control in cases such as this. *Smart*, 70 F.3d at 178 (citation omitted). It would flout these canons to disregard the plain language of the Settlement Agreement and Release and embark on an inquiry into the parties' subjective beliefs. *See generally Newport Plaza Assocs., L.P. v. Durfee Attleboro Bank (In re Newport Plaza Assocs., L.P.)*, 985 F.2d 640, 646-47 (1st Cir. 1993). Those beliefs not only likely would conflict – especially if the Court were to solicit the views of the numerous parties to other approved AWP settlements with identical "any and all drugs" release language (followed by specific examples

said to be "without limitation")[7] – but also almost certainly would be subject to challenge and perhaps further litigation.[8]

Fundamental canons of contract law do not allow a signatory to say after the fact that it only intended to settle claims that are "present in a complaint" where – as here and in other AWP settlements this Court has approved – the governing release says that the intention is to resolve "fully, finally, and forever" not only "claims that were brought" but also those that "could have been brought, or could be brought in the future." *See* Settlement Agreement and Release Section II.J. Nor do those canons permit a signatory to disavow other terms of a release that may not match exactly with the description of claims in a complaint. A written release is intended to avoid these uncertainties. It is indeed intended to "fully, finally, and forever" resolve the endless questions that would arise if subjective intent were the guide.

Moreover, as the Eighth Circuit has observed, it is to be expected that a defendant seeks both breadth and clarity in a release:

> There is no impropriety in including in a settlement a description of claims that is somewhat broader than those that have been specifically pleaded. *In fact, most settling defendants insist on this.*

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[7] Declaration of Shamir Patel in Support of Reply Memorandum of Baxter Healthcare Corporation in Support of Its Motion for Partial Summary Judgment ("Patel Reply Decl.") Exhibit ("Ex.") A at Section II.F., Ex. B at Section II.C., Ex. C at Section II.H.; *see also* Patel Reply Decl. Ex. D at Settlement Agreement and Release at Section II.I., Ex. E at Settlement Agreement at Section II.F.

[8] Relators claim that "Baxter has judicially admitted that Relators Sun and Hamilton filed the first, any only, claims" about Advate. Relators' Memorandum at 1. This is not so. Baxter did choose to file a first-to-file motion only with respect to Recombinate, but that was because, among other reasons, the Recombinate duplication is so clear. This is hardly a judicial admission that Relators' Advate claims were distinct or meritorious. *See id.* at 4. Baxter did not file a motion to dismiss with respect to Ms. Sun's retaliation claims either, yet Baxter believes these claims are completely meritless. Litigation strategy is not tantamount to judicial admission.

Berardinelli v. Gen. Am. Life Ins. Co. (In re Gen. Am. Life Ins. Co. Sales Practices Litig.), 357 F.3d 800, 805 (8th Cir. 2004) (emphasis added).

The *quid pro quo*, of course, for the clarity of a release is the defendant's payment. In this and other AWP settlements, defendant payments have generated hundreds of millions of dollars to the U.S. Treasury.[9] At the end of the day, the Settlement Agreement and Release simply adopts language this Court has previously approved and to which DOJ has consented in other non-intervened AWP settlements.[10] The settling defendants in these cases are entitled to rely upon the plain terms of the negotiated settlements to which the United States consented before they paid these large sums.

II. EVEN IF RELATORS' ADVATE CLAIM WERE NOT BARRED BY THE SETTLEMENT AGREEMENT AND RELEASE, THE CLAIM WOULD STILL FAIL AS A MATTER OF LAW UNDER THE UNDISPUTED FACTS

Relators largely ignore the specific knowledge the Federal Government possessed before Advate's commercial release in August 2003 about AWPs and actual transaction prices for blood-clotting therapies by Advate's commercial release in August 2003. We ask this Court to take judicial notice of its *own* rulings which, after an extensive trial, concluded that there can be no doubt that by late 2003, sophisticated payors like Medicare and Medicaid were well aware

[9] The huge recoveries the United States has received from these settlements, as pointed out previously (*e.g.*, Baxter's Memorandum at 12 n.13), exist largely because defendants have been promised release protection in clear and unequivocal terms. Relators' argument that public policy favors a court's rewriting their releases in these cases (Relators' Memorandum at 7-8) ignores the economic realities, would radically upset the private enforcement scheme Congress has established, and would overthrow the parties' reasonable expectations – all to the disadvantage of the United States in the long run.

[10] The fact that the release language in the agreement between Ven-A-Care and Baxter is similar to language used to settle AWP *qui tam* cases against Teva, Mylan, Watson, Par, and Sandoz is, of course, further evidence that the release was not the result of some plot by Baxter to "hoodwink" the United States Government, as claimed by Relators.

that AWPs did not reflect transaction prices, and therefore they could not be defrauded.[11] As this Court noted, "[t]he statute and the legislative history [of the Medicare Modernization Act] indicate that by 2003, [AWP] had become a term of art. At that point, Congress clearly did understand AWP was different than average sales price and was not reflective of actual prices in the marketplace." *In re Pharm. Indus. Average Wholesale Price Litig. (Track One)*, 460 F. Supp. 2d 277, 288 (D. Mass. 2006).

This knowledge was very specific as to the spreads between the AWPs and actual transaction prices for blood-clotting therapies. To illustrate the Government's specific, detailed knowledge of Advate's pricing and reimbursement, we briefly summarize two letters in the public record of the *Weems* litigation (discussed in Baxter's Memorandum at 9-10, 24) and then respond to Relators' legal argument.

The letters (attached hereto as Patel Reply Decl. Exs. F and G) were Exhibits 2 and 3 to the United States' Memorandum of Points and Authorities in Opposition to Plaintiff's Motion for a Preliminary Injunction. Baxter sent the letters in 2003 and 2004 to the CMS to urge that Advate be assigned, first, a temporary S-Code and, later, a permanent, unique HCPCS J-Code as the first Factor VIII recombinant clotting therapy to be prepared without the addition of any human or animal-derived raw materials. These letters commenced a years-long, unsuccessful effort to secure an Advate-specific reimbursement classification. This quest ended in the

[11] This Court has ruled that "[b]y the mid-1990's, information about the existence of mega-spreads began to seep into the marketplace," *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 40 (D. Mass. 2007), *aff'd*, 582 F.3d 156 (1st Cir. 2009), *cert. dismissed*, 131 S. Ct. 60 (2010); that by August 1997, information was widely available demonstrating that AWP-based reimbursement did not accurately reflect acquisition costs, *id.* at 78-79; and, that "[b]y 2001, there was a perfect storm of information that reflected the size of the spreads, largely because of the compelling information collected by the HHS Office of Inspector General," *id.* at 41. With the passage of the Medicare Modernization Act in June 2003, this knowledge became indisputable.

decision by the United States District Court for the District of Columbia in *Weems*, which found the CMS-designated reimbursement to be unfair to Baxter under the circumstances surrounding the actual pricing and reimbursement of Advate, but nonetheless statutorily correct. *Weems*, 643 F. Supp. 2d at 118.

The first Baxter letter, dated November 10, 2003, furnished CMS with detailed information as to current published AWPs for the four Advate NDCs (Patel Reply Decl. Ex. F at 11) *and* with specific information as to the "actual cost paid by hospitals net of all discounts, rebates, and incentives in cash or in kind" for the same NDCs (*id*. at 12). The second Baxter letter, dated March 16, 2004, provided similar, specific, updated Advate pricing information to CMS. (Patel Reply Decl. Ex. G at 12-13).

These specific pricing disclosures by Baxter to CMS concerning Advate within months of Advate's introduction into the market in August 2003 are examples of the intense scrutiny Baxter itself requested and received from the Federal Government with respect to Advate's AWPs and Advate's actual transaction prices. Thus, Baxter's partial summary judgment motion is not grounded, as Relators contend, in arguments about "generalized knowledge of AWP manipulation." Relators' Memorandum at 1. To the contrary, it is anchored in years of rising government knowledge about the pricing and reimbursement of blood-clotting therapies, culminating in CMS's specific, detailed knowledge of both Advate's published AWPs and its actual transaction prices.

Relators make much of the fact that sometimes those involved in the Medicaid program may not always have the same level of knowledge as those involved in Medicare. *E.g.*, *id*. at 11-12. Placing to one side the underlying legal problem with this argument in this case – since Relators are asserting an FCA claim on behalf of the United States with respect to the

federal share of Medicaid – the fact is that, at the federal level, the Administrators of both programs were fully aware of the material facts relating to Advate's pricing. Baxter provided the Advate pricing information to *CMS*, and CMS has a dual role with respect to overseeing both programs.

Relators also base their arguments on misstatements of the law. First, Relators contend that "government knowledge does not negate the falsity of a claim." Relators' Memorandum at 10. In the very case upon which Relators principally rely, *Massachusetts v. Mylan Laboratories*, 608 F. Supp. 2d 127 (D. Mass. 2008) ("*Mylan*"), however, this Court sustained the viability of that defense where Mylan asserted that the Government came to know that "WACs for generic drugs were false in certain respects" but "decided to continue using WACs as a policy matter." *Id.* at 150, 152. Here, by the time the Government began reimbursing for Advate, Congress was insisting as a policy matter upon using higher published ("term of art") AWPs to reimburse for blood-clotting therapies, *see In re Pharm. Indus. Average Wholesale Price Litig. (Track One)*, 460 F. Supp. 2d at 288, and CMS itself possessed detailed pricing information as to Advate AWPs and transaction prices. Again, the government knowledge defense is not merely viable here, it is dispositive.[12]

Second, Relators grossly misstate the holding of *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F. Supp. 2d 20 (D. Mass. 2007), *aff'd*, 582 F.3d 156

[12] Moreover, Relators ignore the relationship between government knowledge and the elements of scienter and materiality. Proof of the Government's knowledge negates the scienter element "'when the government's knowledge of * * * a [defendant's] actions is *so extensive* that the [defendant] could not as a matter of law possess the requisite state of mind to be liable under the FCA.'" *Mylan*, 608 F. Supp. 2d at 149 (brackets in original) (citation omitted). Also, the extensive government knowledge and acquiescence here make it impossible for Relators to prove the materiality of any allegedly false claim. *See United States ex rel. Williams v. Renal Care Grp., Inc.*, No. 4:05CV985-DJS, 2008 WL 5233028, at *2 (E.D. Mo. Dec. 12, 2008) (government knowledge is relevant to materiality).

(1st Cir. 2009), *cert. dismissed*, 131 S. Ct. 60 (2010). Relators say that this Court there found that "the expected cost of storing and administering the drugs would require a margin of no greater than 20-25%" and that "to the extent that any manipulation of the Average Wholesale Price was to be 'expected,' that manipulation should have been no greater than 30% of the pharmacy acquisition cost." Relators' Memorandum at 11. This Court made no such finding. The case did not involve the type of drugs that are at issue here – namely, blood-clotting factor therapies used to treat hemophilia. In fact, this Court pointed out that the cross-subsidization arguments to be made for hemophilia therapies – which would include the costs of administration for these drugs and risks like spoilage – did not apply to the drugs that were at issue in that case. *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 37-38.

III. RELATORS ARE NOT ENTITLED TO ADDITIONAL DISCOVERY UNDER RULE 56

Relators have made the incredible assertion that they are entitled to additional discovery under Fed. R. Civ. P. 56(d) because Baxter's "government knowledge" defense has taken them by surprise. *See* Decl. of Mark Allen Kleiman Pursuant to Fed. R. Civ. P. 56(f)[13] [Master Docket No. 7903] ¶ 5 ("Relators in good faith did not anticipate Baxter's claim and did not have a prior opportunity to conduct discovery on this topic."). If Relators are surprised by this defense, they have not been paying any attention to the AWP litigation, or even to the papers filed in their own case. Baxter's initial Motion to Dismiss and related papers, filed on August 14, 2009 [Sun Sub-Docket Nos. 65-67], cited to and attached numerous government reports reflecting the Government's knowledge of the difference between AWPs and transaction prices. On April 14, 2010, then-defendant Baxter International Inc. filed its Answer [Sun

[13] Relators seek relief under Fed. R. Civ. P. 56(f); this Rule was recently renumbered 56(d).

Sub-Docket No. 95]. In that Answer, Baxter raised the following as its Second Affirmative Defense:

> Relators' claims are barred, in whole or in part, because the United States Government and/or the States did not rely on any alleged misrepresentations or fraud by Baxter International. The U.S. Government and/or the States knew that providers could obtain Baxter Healthcare Corporation drugs and therapies at prices below the published AWP prior to and throughout the relevant time period stated in the Petition.

Baxter raised this verbatim Second Affirmative Defense in the Answer filed by Baxter Hemoglobin Therapeutics [Sun Sub-Docket No. 94] and later in the Answer of substituted defendant Baxter Healthcare Corporation [Sun Sub-Docket No. 103]. Finally, Baxter served third-party subpoenas on CMS, various Medicare carriers, and numerous State Medicaid programs during the course of the discovery period. Copies of all of these subpoenas were served on counsel for Relators.

In short, Relators have absolutely no basis to claim "good faith" surprise concerning Baxter's government knowledge defense, and therefore no basis to take additional discovery at this point, *a week before the expiration of the discovery period*.[14] As this Circuit has warned, "'Rule 56(f) is not designed to give relief to those who sleep upon their rights.'" *Dennis v. Osram Sylvania, Inc.*, 549 F.3d 851, 860 (1st Cir. 2008) (citation omitted). In order to be granted discovery under Rule 56, a movant must, among other things, "demonstrate good cause for failure to have conducted the discovery earlier." *Paterson-Leitch Co. v. Mass. Mun. Wholesale Electric Co.*, 840 F.2d 985, 988 (1st Cir. 1988). This Relators cannot do. Accordingly, Relators' request for discovery under Rule 56 should be denied.

[14] Pursuant to this Court's June 28, 2011 Order, fact discovery in this matter closes December 1, 2011.

IV. CONCLUSION

For the reasons argued above, the Court should grant Baxter's Motion for Partial Summary Judgment and dismiss with prejudice Count I of the Complaint.

Dated: November 28, 2011

/s/ Shamir Patel
J. Andrew Jackson
Merle DeLancey
Shamir Patel
DICKSTEIN SHAPIRO LLP
1825 Eye Street NW
Washington, DC 20006
Telephone: (202) 420-2200
Facsimile: (202) 420-2201

Peter E. Gelhaar (BBO #188310)
DONNELLY, CONROY & GELHAAR, LLP
One Beacon Street, 33rd Floor
Boston, MA 02108
Telephone: (617) 720-2880
Facsimile: (617) 720-3554

Counsel for Defendant Baxter Healthcare Corporation

CERTIFICATE OF SERVICE

I hereby certify that I, Shamir Patel, an attorney, electronically filed the foregoing REPLY MEMORANDUM OF BAXTER HEALTHCARE CORPORATION IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT with the Clerk of the Court for the District of Massachusetts using the Court's CM/ECF system on November 28, 2011. I also caused a true and correct copy of the foregoing document to be delivered to all counsel of record by electronic service via LexisNexis File & Serve, for posting and notification to all parties.

/s/ Shamir Patel

Shamir Patel
DICKSTEIN SHAPIRO LLP
1825 Eye Street NW
Washington, DC 20006
Telephone: (202) 420-2200
Facsimile: (202) 420-2201